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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/727,317 | 12/03/2003 | Akito Ichida | Furuya Case 1410 | 6210 |

1095 7590 06/08/2005

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER

OH, TAYLOR V

ART UNIT PAPER NUMBER

1625

DATE MAILED: 06/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|---|--------------------------------------|--------------------------------------|--|
| Advisory Action Before the Filing of an Appeal Brief | Application No. 10/727,317 | Applicant(s) ICHIDA, AKITO | |
| | Examiner Taylor Victor Oh | Art Unit 1625 | |

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 09 May 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
 (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
 (b) ☐ They raise the issue of new matter (see NOTE below);
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
 5. ☐ Applicant's reply has overcome the following rejection(s): _____.
 6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
 The status of the claim(s) is (or will be) as follows:
 Claim(s) allowed: _____.
 Claim(s) objected to: 5 and 6.
 Claim(s) rejected: 1, 2 and 4.
 Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see pages 2-5.
 12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____.
 13. ☐ Other: _____.

S.O.O.

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It is noted that applicants have filed an Amendment after the Final Rejection on 5/9/05; applicants' attorney has addressed the issues of record. The proposed amendment will be entered ; however, it is not in a condition for allowance.

The Status of Claims

Claims 1-2 and 4-6 are pending.

Claims 1-2 and 4-6 have been rejected.

Claims 5-6 have been objected.

Claim Objections

Claims 5-6 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections-35 USC 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of Claim 5 has been withdrawn due to the modification made in the amendment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The rejection of Claims 1-2 and 4 under 35 U.S.C. 103(a) as being unpatentable over Grella et al (J. Med. Chem. P. 4726-4737, 2000) in view of Metzger (U.S. 3,972,910) has been maintained for the reasons of the record on 8/24/04.

Applicants' attorney has addressed the issues of record; however, has not rebutted the claim rejections 1-2 and 4 under 35 USC 103 (a).

Applicants' Argument

I. Applicants argue the following issues:

1. when Metzger's N-chlorosuccinimide is used, succinimide is produced as a side-product and cannot be separated out by filtration due to its low solubility unlike the present invention which uses t-butylhydrochloride enables the product to be produced in a high purity.

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2. The present invention results in an unexpected improvement in high production yield of the product in comparison with the Grella et al process.

The applicants' argument have been noted, but these arguments are not persuasive.

First, with respect to the first and second arguments, the Examiner has noted applicants' argument. However, the claim is directed to the process for preparing 3-chloro-5-nitrotoluene ; Metzger expressly teaches that the chlorination of the aminotoluene ring can be achieved either by N-chlorosuccinimide or t-butylhypochlorite (see col. 2 ,lines 43-51). Similarly , Grella et al expressly teaches the preparation of 3-chloro-5-nitrotoluene by reacting 2-methyl-4-nitroaniline with the N-chlorosuccinimide chlorinating agent. From this, there is a teaching of equivalence between N-chlorosuccinimide and t-butylhypochlorite. Furthermore, both prior art have been dealt with the chlorination of the aromatic compound with the substituents of methyl and amino groups. With the guidance of the Metzger teaching, therefore, it would have been obvious to the skilled artisan in the art to be motivated to employ Metzger's t-butylhypochlorite as an alternative to the N-chlorosuccinimide chlorinating agent in the Grella et al process because the skilled artisan in the art would expect such a modification to be effective and successful as shown in the Metzger.

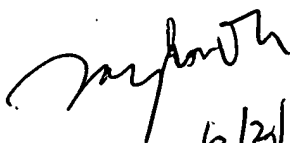
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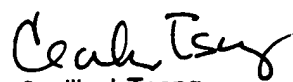
So far , there is no Declaration filed with the side-by-side comparison with respect to the unexpected result between the Grella et al prior art process and the currently claimed invention; therefore, applicants' mere argument about the unexpected result is of little value. The Examiner recommends applicants to file the Declaration regarding the unexpected result with the proper comparison between them. Until then , the rejection is to be maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


6/23/05


Cecilia J. Tsang
Supervisory Patent Examiner
Electronic Business Center 1600